AUG 2 7 2003

Section 6 — 510(k) Summary

(Pursuant To 21 CFR 807.92)

6.1 General Provisions

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, Minnesota 55311
Contact Person	Todd Kornmann (763) 494-2467
Classification Name	Biliary Catheter and Accessories Product Code – 78 FGE Regulation Number 21 CFR Part 876.5010
Common or Usual Name	Biliary Stent and Balloon Dilatation Catheter
Proprietary Name	Boston Scientific Corporation Express Biliary LD Premounted Stent System and Express Biliary LD Unmounted Stent.

6.2 Name of Predicate Device

Boston Scientific Express Biliary LD Premounted Stent System and Express Biliary LD Unmounted Stent

6.3 Device Description

Stent Description

The 5 mm Express Biliary LD Stent (Premounted Stent System and Unmounted Stent) are identical to the currently marketed Express Biliary LD Premounted Stent Systems (K021630 and K024048) and to the currently marketed Express Biliary LD Unmounted Stents (K030645), with the exception of size.

The Express Biliary LD Stent is a balloon expandable 316L surgical grade stainless steel stent intended to maintain patency of biliary strictures produced by malignant neoplasms. The stent will be available in a variety of sizes to address clinician needs.

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The currently marketed Express Biliary LD Premounted Stent System and Express Biliary LD Unmounted Stent are offered with stent diameters of 6 – 10 mm, in one mm increments. The 6 – 8 mm diameter stents have lengths of 17 mm, 27 mm, 37 mm, and 57 mm. These are considered to be the Small Lumen (SL) models. The 5 mm diameter is proposed for these stent lengths and is the subject of this submission.

The 9 mm and 10 mm diameter stents have lengths of 25 mm, 37 mm, and 57 mm. These are considered to be the Large Lumen (LL) models.

Express Biliary LD Premounted Balloon Delivery Catheter

The balloon delivery catheter for the 5 mm Express Biliary LD Premounted Stent System is identical to the balloon delivery catheter utilized on the currently marketed Express Biliary LD Premounted Stent Systems (K021630 and K024048). The balloon delivery catheter is an over-the-wire catheter offered in a two lumen catheter shaft design.

Express Biliary LD Unmounted Stent Recommended Delivery Catheter

The delivery catheter recommended for use with the 5 mm Express Biliary LD Unmounted Stent is the currently marketed Boston Scientific Ultra-thin SDS Balloon Dilatation catheter (K011889 and K011909). The Ultra-thin SDS catheter was determined substantially equivalent for PTA indications under K011889, and for the indication of stent deployment / optimization of a Biliary Stent under K011909.

The recommended delivery catheter, the Ultra-thin SDS Balloon Dilatation Catheter, is the identical catheter that is utlized for the Express Biliary LD Unmounted Stents cleared to market under K030645. The Ultra-thin SDS Balloon Dilatation Catheter is an over-the-wire catheter offered in a two lumen catheter shaft design.

A more detailed device description is provided in the original 510(k) applications (K011909 or K011889, Attachment A, Device Description) and is also provided in Section 8 of this submission.

6.4 Intended Use

The Express Biliary LD Stent is indicated for the treatment of biliary strictures produced by malignant neoplasms.

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6.5 Comparison of Required Technological Characteristics

The Boston Scientific 5 mm Express Biliary LD Stent will incorporate the identical design, method of deployment, fundamental technology, manufacturing, packaging, labeling, sterilization, and intended use as those in the currently marketed the Express Biliary LD Premounted Stent System (K021630 and K024048) and Express Biliary LD Unmounted Stents (K030645).

6.6 Summary of Non-clinical Test Summary

The safety and effectiveness of the the 5 mm Express Biliary LD Stent in both the Premounted an Unmounted models have been demonstrated via data collected from non-clincal design verification tests and analyses.

Sterilization, biocompatibility, product and packaging shelf life testing have also been evaluated. Test results verified that the 5 mm Express Biliary LD Stent is adequate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2003

Mr. Todd Kornmann
Sr. Regulatory Affairs Specialist
Boston Scientific Corporation
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K032360
Trade/Device Name: Boston Scientific Express™ Biliary LD Premounted Stent System and Express™ Biliary LD Unmounted Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: August 1, 2003
Received: July 31, 2003

Dear Mr. Kornmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K032360

Device Name: Boston Scientific Express™ Biliary LD Premounted Stent System and Express™ Biliary LD Unmounted Stent

FDA's Statement of the Indications For Use for device:

The Boston Scientific Express™ Biliary LD Stent is indicated for the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

David A. Segraves
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032360